



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,745	03/30/2001	Tom L. Blundell	620-139	4747

23117 7590 05/12/2005

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

NASHED, NASHAAT T

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/820,745

Applicant(s)

BLUNDELL ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 5-8, 11 and 14-16.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).


10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.


Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit: 1652

Art Unit: 1652

Claims 5-8, 11, and 14-16 are pending and under consideration.

The drawing filed December 22, 2004 have been accepted by the examiner.

The filing of the substitute specification fails to comply with 37 CFR 1.125 (b) which is stated below:

§ 1.125 Substitute specification.

(b) Subject to § 1.312, a substitute specification, excluding the claims, may be filed at any point up to payment of the issue fee if it is accompanied by a statement that the substitute specification includes no new matter.

Applicants must file a statement indicating that the substitute specification filed 4/27/05 includes no new matter.

Applicant must perfect their compliance with the sequence rules, 37 CFR 1.821(a)(1) and (a)(2). Applicants must insert the sequence identification number in either the figure description or file a new figure containing the sequence identification numbers. In addition, applicants must insert the sequence identification number after each occurrence of KPHMT.

Applicants have made an attempt to comply with the sequence rules, but their efforts fail short. The insertion of SEQ ID NO: 7-11 after each occurrence of KPHMT is considered inadvertent misleading statements and a new matter. At page 15 for example, the specification describes the expression of a clone named pAL01, which, presumably, contains a single coding sequence to one of the proteins of SEQ ID NO's: 7-11. The examiner considers the crystallization of five different proteins under the same conditions to produce identical crystals with identical atomic coordinates, which are listed in Table 1, is not possible. The amino acid sequence listed in Table 1 is the 264 amino acid residues of the amino acid sequence of SEQ ID NO: 7. As indicated in the previous Office action mailed February 28, 2005, the Tables constitute a disclosure of amino acid sequences and therefore, Table 1 should have a title containing the sequence identifier of SEQ ID NO: 7.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1652

Claims 5-8 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the commercial availability of computers and various software packages such as RASMOL, see the specification the paragraph bridging page 12 and 13, an admitted prior art, in view Jones *et al.* [IDS reference: J. Bacteriol. 1993, Vol. 175, pages 2125-2130] for the reasons set forth in the prior Office action mailed September 22, 2004.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the fact that homology modeling methods are well known in the prior art, see the specification on page 11, lines 23-25, in view Kurtov *et al.* [IDS reference: Mol. Gene. Genet. 1999, Vol. 262, pages 115-120] for the reasons set forth in the prior Office action mailed September 22, 2004 and February 28, 2005.

Applicants argue that the rejection is not consistent with the law and the direction of the court *in re Gulack* with regard to printed material. They argue that the examiner can't dissect a claim, excise the printed matter from it and declare the remaining portion of the mutilated claim to be unpatentable, and should consider the claim as a whole. In addition, they argue that trilateral report does not have the effect of law, and at best, is the interpretation of the law by the Patent Office.

Applicants' arguments filed 4/27/05 have been fully considered, but they are found unpersuasive. Applicants are correct in that the Trilateral report is not a law, and it is the interpretation of the Patent Office of the law. The law, however, gives the Patent Office the authority to interpret the law until the court provides the Patent Office with further teaching and guidance. Per guidance of the court decision *in re Gulack*, the examiner consider the claims as a whole, and did not dissect a claim, excise the printed matter from it and declare the remaining portion of the mutilated claim to be unpatentable. The facts, that methods of identifying agents that binds and inhibit the activity of an enzyme and homology modeling methods are well-known in the prior art and computers equipped with the appropriate software to design inhibitor for any enzyme with known structural coordinates are commercially available, are not in dispute. In considering the claim as a whole, the question of the effect of the novel atomic coordinate on the known methods and computers had to be addressed. The atomic coordinates do not change either the computer or the algorithms, and consequently the methods for inhibitors design. The methods of designing inhibitors utilizing atomic coordinate are applicable to any enzyme/protein regardless of its function. The guidance of the court *in re Gulack* clearly divides the printed material in two categories. The court writes:

"Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight. However, because we find that the digits of Gulack's invention are functionally related to the band, and because Wittcoff fails to disclose or suggest the subject matter recited in the appealed claims, considered as a whole, we reverse."

Art Unit: 1652

In the instant case, the substrates are the algorithms and computers required for designing inhibitor. Both the computer and algorithms are functional with any set of atomic coordinates. The atomic coordinates in Table 1 do not modify the computer or algorithms in any way, and therefore, do not alter the claimed method. That is the reason why the atomic coordinates are considered "nonfunctional descriptive materials", and not given a patentable weight. Thus, the examiner has not dissected the claims, excised the printed matter from it and declared the remaining portion of the mutilated claims to be unpatentable. The examiner has considered the claimed invention as a whole. The rejection of the claims remains proper under the law.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1652